

# EVOLUTION OF TESTING AND ASSESSMENT METHODS IN CHEMICALS POLICY PROGRAMS AND IMPLICATIONS FOR EPIDEMIOLOGY AND CHILDREN'S HEALTH

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**Background and aims:** Policies for safety of industrial chemicals and chemicals used in products are receiving attention. The European Union (EU) is implementing its comprehensive chemicals management program, known as REACH. The United Nations is coordinating the Globally Harmonized System for labeling and classification. In the United States (US), the Congress has debated amending the Toxic Substances Control Act, and many states have enacted elements of chemicals policy reform. With this discussion is increased scrutiny of methods for chemicals testing and assessment. Both the US and the EU are engaged in processes to move chemicals testing and assessment from methods largely based on the use of animal models and epidemiology to methods based largely on assays and "high throughput" methods. The US National Academy of Sciences recommended such approaches in 2007. This is an analysis of the trajectory of this process and its implications.

**Methods:** The documentation for testing and assessment requirements for REACH, the GHS, and US programs was reviewed with regard to hazard traits. Literature regarding the development and evolution of new methods available from the US Environmental Protection Agency (US EPA), the National Institute of Environmental Health Sciences (NIEHS), and REACH was reviewed.

**Results:** The US and European processes are evolving differently, with the EU focused on substitution of new methods for older methods and the US focused on mechanisms of toxicity and markers. Neither has defined a set of goals that would encompass significant concerns for children, particularly developmental neurotoxicity, immune effects, or lung development. Though the management regimes refer to use of epidemiological data, the approaches to new methods do not seem to be incorporating epidemiology into validation or verification approaches. Methods for interpretation of data in policy contexts are also not yet well developed.

**Conclusions:** Additional attention is needed in these areas.